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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,826	01/31/2001	John D. Roback	050508-1030	7152

7590 03/25/2005

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/773,826

Applicant(s)

ROBACK ET AL.

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Yaremko.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample (col. 13, line 61 – col. 15, line 3). The

Art Unit: 1743

imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 11 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), (col. 13, lines 1-12).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2-6, 8, 11 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US patent 5,308,990 to Takahashi et al.

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, as recited in claims 1 and 25 (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material, as recited in claims 1, 3 and 4. The beads have a size of 10-100 microns, as recited in claim 5. See col. 6, lines 9-32. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 1, 8, 25 and 27 (col. 13, line 61 – col. 15, line 3). The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 11 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises

Art Unit: 1743

a pipette (402) and a robot arm (404), as recited in claim 1 (col. 13, lines 1-12). With respect to the washer recited in claim 2, Yaremko et al teach that washers (406, 410) contain liquids for rinsing or cleaning (col. 13, lines 23-28).

Yaremko et al differs from the instant invention in that it teaches a camera to image the analysis results, whereas Applicants claim the use of flow cytometer.

Takahashi et al teach that flow cytometers can be used in immunological measurement methods to determine antigen-antibody reactions and agglutination from the antigen-antibody reactions (col. 1, lines 37-53). It would have been obvious to one of ordinary skill in the art to substitute the camera system of Yaremko et al for a flow cytometer to provide a means to determine antigen-antibody interactions and agglutination in immunological assays.

5. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al and Takahashi et al, as applied above, and further in view of US Patent 5,603,899 to Franciskovich et al.

The disclosures of Yaremko et al and Takahashi et al are described above. Neither Yaremko et al nor Takahashi et al teach a vacuum system for separating the sample.

Franciskovich et al teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 25-31. Thus, it would have been obvious to substitute the centrifuge assembly of Yaremko et al with a vacuum assembly as disclosed by Franciskovich et al to allow simultaneous separation of multiple samples and thus increase the sample processing time.

Art Unit: 1743

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al and Takahashi et al, as applied above, and further in view of US Patent 6,008,040 to Datar.

The disclosures of Yaremko et al and Takahashi et al are described above. Neither Yaremko et al nor Takahashi et al teach the particular filter materials recited in claim 7.

Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Information Disclosure Statement

The items listed in the Information Disclosure Statement filed on January 28, 2005 has been considered. However, each item referring to correspondences from the European patent office has been lined through, as such information is not printed on the published patent. The information has been made a part of the official record.

Response to Arguments

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Maureen M. Wallenhorst
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